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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,072	12/04/2003	Ron Heil	GUID.626PA	7645

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MINNEAPOLIS, MN 55425

EXAMINER
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KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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07/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/728,072

Applicant(s)

HEIL ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-66 is/are pending in the application.
- 4a) Of the above claim(s) 33-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-32 and 48-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/2007 has been entered.

### ***Response to Amendment***

2. The status identifiers for claims 33-47 do not indicate that the claims are withdrawn. The claims should be corrected accordingly.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4-7, 9, 13, 15, 18, 19, 21, 22, 27, 28, 30, 48, 49, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (US 6,282,444, hereinafter "Kroll").

5. In regards to claims 1, 18, 21, and 48, Kroll discloses a device that comprises a lead body (74 and 76), a cardiac electrode capable of subcutaneous non-intrathoracic placement for cardiac monitoring and cardiac stimulation (col. 3, line 46 and col. 12, line 13), one or more conductors within the lead body (col. 5, line 53), a pharmacological agent provided along an exterior surface of the lead body/can (col. 11, line 65), and a driving arrangement to drive the agent from the exterior surface to subcutaneous tissue (col. 11, line 58). Please note that, because the biocide is applied "surrounding the cardiac stimulation device" and the "cardiac stimulation device" comprises the housing and lead, Kroll's device anticipates the claim limitations. Additionally, claim 55 does not require that the first and second pharmacological agents are different drugs. Therefore, the "first pharmacological agent" is the portion of the biocide that surrounds the lead, and the "second" agent is the agent that surrounds the can.

6. In regards to claims 2, 19, and 49, the driving arrangement comprises an electrode on the lead body/can (128, 130 and 138) that is adapted to provide electrophoresis because it provides an electric field (i.e. the electrodes "are adapted to provide electrophoresis", regardless of whether there is an ionic substance present).

7. In regards to claim 4, the electrode is an electrode array (130 and 138).

8. In regards to claim 6, the pharmacological agent provides therapeutic treatment systemically as well as locally (col. 11, line 50), thusly including a dissection path.

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9. In regards to claim 7, the agent is provided over a plurality of arbitrarily chosen portions of the surface of the lead body.

10. In regards to claim 9, the agent is provided at the "collar" electrodes (130 and 138).

11. In regards to claims 13, 27 and 28, the agent is provided in a coating of at least 25% because the agent "surrounds" the device.

12. In regards to claims 15, 30, and 52, the agent is an antibiotic (col. 11, line 65).

13. In regards to claims 22, the lead and can produce an electric potential between the two (136 and 142).

14. Claims 1, 2, 4-7, 11, 16-19, 21, 22, 25, 31, 32, 48, 49, 53, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Darvish et al. (US 7,190,997, hereinafter "Darvish").

15. In regards to claims 1, 18, 22, and 48, Darvish discloses a device that comprises a lead body (104), a cardiac electrode capable of subcutaneous non-intrathoracic placement for cardiac monitoring and cardiac stimulation (col. 5, line 59), one or more conductors within the lead body (Figs. 3A-E), a pharmacological agent provided along an exterior surface of the lead body/can (col. 5, line 8; col. 6, line 30; col. 13, line 65, col. 15, line 12, and col. 16, line 23), and a driving arrangement to drive the agent from the exterior surface to subcutaneous tissue (col. 4, line 67).

16. In regards to claims 2 and 21, the driving arrangement comprises an electrode supported by the lead body (182).

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17. In regards to claim 4, the electrode is an electrode array (col. 14, line 32).
18. In regards to claims 5, 19 and 49, the arrangement provides electrophoresis (col. 6, line 56).
19. In regards to claim 6, the agent provides therapy to an area localized to a dissection path (col. 15, line 15).
20. In regards to claim 7, the agent is provided over a plurality of arbitrarily chosen portions of the surface of the lead body.
21. In regards to claims 11 and 25, the lead comprises a porous region containing pharmacological agent (col. 15, line 56).
22. In regards to claims 16, 17, 31, 32, 53, and 54, Darvish's device provides steroids (col. 25, line 65) and an agent that promotes hemostasis (col. 25, line 55).

***Claim Rejections - 35 USC § 103***

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 55, 58, and 64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll. Kroll discloses the essential features of the claimed invention, including providing a first and second pharmacological agents (the agents are not claimed as being different, so the first agent is the agent that surrounds the lead and the second agent is the agent that surrounds the can), and providing driver circuitry separate from the pacing device (col. 12, line 18), inherently disclosing a "detachable coupling". Alternatively, it is well known in the art to provide separate devices with detachable couplings to allow the devices to be implanted separately and later coupled to minimize implantation trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Kroll's device with a detachable coupling to allow the devices to be implanted separately and later coupled to minimize implantation trauma.

26. Claims 55, 56, 65, and 66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Darvish. Davrish discloses the essential features of the claimed invention, including providing multiple agents (col. 9, line 43) and providing a separate driving means (col. 12, line 40-col. 13, line 34). Because the means are separate, they are detachably coupled, such as the embodiment at col. 12, line 64. Alternatively, it is well known in the art to provide separate devices with detachable couplings to allow the devices to be implanted

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separately and later coupled to minimize implantation trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Darvish's device with a detachable coupling to allow the devices to be implanted separately and later coupled to minimize implantation trauma.

27. Claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (or Darvish). Kroll (or Darvish) discloses the essential features of the claimed invention except for a sonophoresis driving mechanism; a pharmacological agent impregnated in a membrane coating; a pharmacological agent infused in a porous doped polymeric structure; or an analgesic/anesthetic agent. It is well known in the art to provide implantable devices with sonophoresis driving mechanisms to provide deeper penetration of non-ionically charged medications; pharmacological agents impregnated in membrane coatings to provide an easily manufactured device with medication delivered over a large surface area of the device; pharmacological agents infused in porous doped polymeric structures to provide slow and controlled release of a drug over a long period of time; and analgesic/anesthetic agents to provide a less painful recovery from implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Kroll's (or Darvish's) invention with a sonophoresis driving mechanism to provide deeper penetration of non-ionically charged medications; a pharmacological agent impregnated in a membrane coating to provide an easily manufactured device with medication delivered over a large surface area of the device; a pharmacological agent infused in a porous doped polymeric structures to provide slow



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and controlled release of a drug over a long period of time; and an analgesic/anesthetic agent to provide a less painful recovery from implantation.

28. Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (or Darvish). Kroll (or Darvish) discloses the claimed invention, including various configurations of the medication/pacing control housing(s) but does not disclose expressly the driver provides a phoresis power signal to the implanted device, wherein the control signal is DC, AC, or AC with a DC offset. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the driver as taught by Kroll (or Darvish) with the various control signals because applicant has not disclosed that AC, DC or AC with DC offset provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the control signal as taught by Kroll (or Darvish) because both systems signal to the drug delivery module when medication is needed. Therefore, it would have been an obvious matter of design choice to modify the control signals as disclosed Kroll (or Darvish) to obtain the invention as specified in the claims.

### ***Response to Arguments***

29. Applicant's arguments with respect to claims 1-23, 25-32, and 48-66 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.


**Conclusion**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

  
7/19/07

  
GEORGE R. EVANISKO  
PRIMARY EXAMINER

7/22/07